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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/505,482      | 08/23/2004  | Klaus Strebhardt     | 2923-656            | 3528             |

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EXAMINER

WOLLENBERGER, LOUIS V

ART UNIT PAPER NUMBER

1635

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/505,482

Applicant(s)

STREBHARDT ET AL.

Examiner

Louis V. Wollenberger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1–23 and 30, drawn generally to an agent that reduces or inhibits the activity of polo like kinase 1 (PLK1) in mammalian cells, and particularly to agents comprising a short interfering RNA (siRNA), antisense RNA, or RNA expression system directed against the PLK1 gene;

Group II, claim(s) 1 and 24–29, drawn generally to an agent that reduces or inhibits the activity of polo like kinase 1 (PLK1) in mammalian cells, and particularly to a peptide that reduces or inhibits the activity of polo like kinase 1 (PLK1) in mammalian cells;

Group III, claim(s) 31, drawn to a method for treating patients, comprising the use of an agent that reduces or inhibits the activity of polo like kinase 1 (PLK1) in mammalian cells.

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The inventions listed as Groups I–VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Groups I and III is considered to be an agent that reduces or inhibits the activity of polo like kinase 1 in mammalian cells. However, this agent cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art. Wolf et al., (2000) *Pathology Research and Practice*, Vol. 196, page 352, teaches the use of antisense oligonucleotides targeted against human polo-like kinase PLK in mammalian cells, as claimed in Claims 1 and 31. The reference states that application of the antisense-PLK oligonucleotide, which corresponded to the 5' untranslated region of the PLK mRNA, reduced cell growth rates by up to 10-fold as compared to untreated controls. The reference specifically suggests that treatment with PLK antisense oligonucleotides could be a strategy in tumor therapy. Thus, Groups I and III lack unity of invention because the special technical feature, an agent that reduces or inhibits the activity of polo like kinase 1 in mammalian cells, does not make a contribution over the prior art.

According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. Groups I and II are each directed to agents that reduce or inhibit the activity of polo like kinase 1 in mammalian cells; however, each group has a different technical feature not shared by the remaining groups. Group I is directed to an agent that reduces or inhibits the activity of polo like kinase 1 in mammalian cells, which has the special technical feature of a

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short interfering RNA, not present in any of the other groups. Group II is directed to an agent that reduces or inhibits the activity of polo like kinase 1 in mammalian cells, which has the special technical feature of a peptide, not present in any of the other groups. Thus, Groups I and II lack unity of invention because they do not share the same or corresponding special technical feature.

***Further Restriction to a Single siRNA Sequence***

Claim 5 specifically claims siRNAs 2, 3, and 4, which are targeted to and modulate the expression of the PLK1 gene. This international searching authority considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2, and 13.3) for the reasons indicated below: According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed siRNA sequences, the Markush group shall be regarded as being of similar nature when (A) all alternatives have a common property or activity and (B)(1) a common structure is present, i.e, a significant structure is shared by all of the alternatives or (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains. The instant antisense sequences are considered to be each separate inventions for the following reasons: the sequences do not meet the criteria of (A), common property or activity or (B)(2), art recognized

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class of compounds. Although the sequence target and modulate expression of the same gene, each siRNA sequence behaves in a different way in the context of the claimed invention. Each sequence targets a different and specific region of the PLK1 gene and modifies the expression of the gene to varying degrees. Each member of the class cannot be substituted one for the other, with the expectation that the same intended result would be achieved. Further, although the sequence target the same gene, the sequences do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the siRNA sequences is lacking and each siRNA sequence claimed is considered to constitute a special technical feature.

### ***Conclusion***

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on Mon–Fri, 8:00 am–4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval system (PAIR). Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within

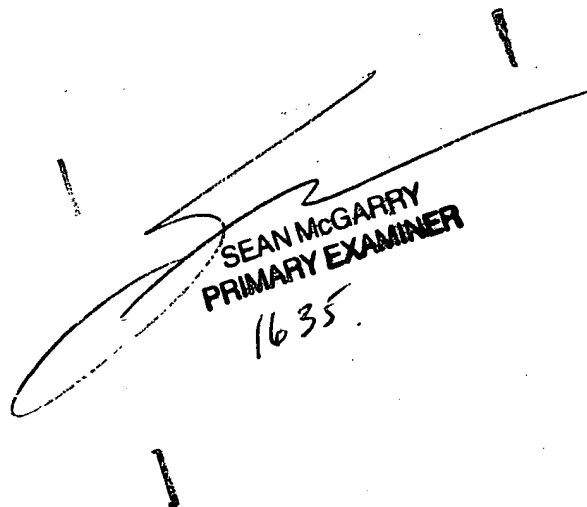
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5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

LVW July 19, 2005

Louis V. Wollenberger, Ph.D.  
Examiner  
Art Unit 1635

  
SEAN MCGARRY  
PRIMARY EXAMINER  
1635